

## REMARKS

### 1. STATUS OF CLAIMS

Claims 30, 31, 33-36, 38-40, 42, 44-46, 51, 67-69, 72, and 86-93 were pending.

In the Action of July 30, 2008, the Examiner stated that claims 30, 31, 33-36, 38-40, 42, 44-46, 51, 67-69, 72, and 86-93 were allowable. In the Action of November 14, 2008, the Examiner withdrew the allowability of those claims and substituted the current rejections.

Applicants cancel claims 33, 38, 39, 40, 42, and 90 without prejudice.

Applicants have amended claim 30 to eliminate the recitation of **biguanide** groups. Applicants have also narrowed the scope of claim 30 to further recite that the coating, layer, or enhanced surface area **consists essentially** of said polymeric molecules. Applicants have narrowed the scope of the claim to recite polymeric molecules **formed by the polymerization of a diallyldialkylammonium salt**. Support for the amendment is found within Table 1, paragraphs [0035] and [0096], and claims 11-14, 25-28, and 39-42 of the specification as originally filed.

Applicants have amended claim 51 to clarify that the **effective amount** refers to **antimicrobial** activity. Support for the amendment is found within the test methods and testing results reported in Example 2. Applicants have narrowed the scope of the claim to recite polymeric molecules **formed by the polymerization of diallyldimethylammonium** chloride, also known as DADMAC. Support for the amendment is found within Table 1, paragraphs [0035] and [0096], and claims 14, 28, and 42 of the specification as originally filed. Claim 51 is amended to properly refer to elements within the claim.

In both claims 30 and 51, Applicants have intentionally eliminated the recitation of "not pendant to the main chain of the polymeric molecules." These claims now recite a specific set of compounds for which that limitation to distinguish from the prior art would be superfluous. The claims as presently written make it immaterial whether or not the quaternary ammonium group is considered to be pendant to the main chain of the polymer, thereby avoiding the need to ascertain and prove this aspect of the molecular structure of an allegedly infringing composition.

Applicants have amended claim 31 to recite that the diallyldialkylammonium salt of claim 30 is a **diallyldimethylammonium** salt. Support for the amendment is found within Table 1, paragraphs [0035] and [0096], and claims 14, 28, and 42 of the specification as originally filed.

Applicants have amended claim 67 to recite polymeric molecules formed by the polymerization of diallyldimethylammonium chloride, also known as **DADMAC**. Support for the amendment is found within Table 1, paragraphs [0035] and [0096], and claims 14, 28, and 42 of the specification as originally filed.

Applicants have amended claims 91 and 92 to correct the antecedent basis so that these claims properly refer to elements of the base claims. The claims have also been amended to recite a **diallyldimethylammonium salt** and **DADMAC**, respectively. Support for the amendment is found Table 1, paragraphs [0035] and [0096], and claims 14, 28, and 42 of the specification as originally filed.

Applicants have amended claims 34, 35, 36, 38, 45, and 72 to correct the antecedent basis so these claims properly refer to elements of claim 30.

Applicants have added new claim 94 which recites that cerium catalyzes the polymerization of DADMAC. Support for the new claim is found in Table 1, claim 38 and paragraphs [0065] and [0068].

Currently, claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-95 are pending.

## **2. THE OFFICE ACTION OF NOVEMBER 14, 2008**

### **Rejections**

The Examiner, in a Non-Final Office Action mailed November 14, 2008, rejected all of the pending claims in the application.

A. Claims 30, 31, 33-36, 38-40, 42, 44-46, 51, 68, 69, 72, 86-91, and 93 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sawan et al. U.S. 6,126,931 ("Sawan") in view of Perrault et al. U.S. 6,039,940 ("Perrault").

B. Claims 67 and 92 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sawan in view of Perrault and further in view of Kolb et al. U.S. 6,797,856 ("Kolb").

## **3. ARGUMENTS AGAINST EXAMINER'S REJECTIONS**

Applicants respectfully traverse the Examiner's rejections of claims 30, 31, 34-36, 38-40, 42, 44-46, 51, 67-69, 72, and 86-93 and request reconsideration and withdrawal of the rejections based on the above claim amendments and the following remarks.

**A. REJECTION OF CLAIMS 30, 31, 33-36, 38-40, 42, 44-46, 51, 68, 69, 72, 86-91, AND 93 UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER SAWAN IN VIEW OF PERRAULT.**

The Examiner asserts that Sawan discloses all aspects of the claimed invention with the exception of the antimicrobial being a quaternary ammonium. The Examiner asserts that Sawan discloses antimicrobial compositions comprising a substrate, a coating layer comprising a polymeric material which is non-leachably bound by covalent bonds to the substrate. Perrault teaches the use of quaternary ammonium groups to provide antimicrobial activity to a polymeric material. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the quaternary ammonium groups of Perrault with the polymeric material of Sawan to obtain the present invention as recited in claims 30, 31, 33-36, 38-40, 42, 44-46, 51, 68, 69, 72, 86-91, and 93. Applicants respectfully disagree.

The rejection is moot with respect to claims 33, 38, 39, 40, 42, and 90 because those claims have been canceled. Applicants assert that the combination of Sawan and Perrault do not make claims 30, 34-36, 44-46, 51, 68, 69, 72, 86-89, 91, 93, and 94 obvious to one of ordinary skill in the art at the time the invention was made.

Sawan discloses that a coating layer may be comprised of organic materials including (a) benzalkonium chloride derivatives, (b)  $\alpha$ -4-[1-tris(2-hydroxyethyl) ammonium-2-butenyl] poly [1-dimethylammonium-2-butenyl]- $\omega$ -tris(2-hydroxyethyl) ammonium chloride ("DMABHEAC"), and (c) biguanides and their polymers [col 8, ln 63-67]. Sawan does not disclose or suggest that a polymer formed by the polymerization of a diallyldialkylammonium salt would be a useful coating layer.

Sawan does not expressly state that the organic materials that coat the surfaces are not inherently antimicrobial. However, Sawan consistently teaches that a biocide (or antimicrobial substance) be nonleachably bonded with, or complexed to, the organic matrix and that the **combination** gives the surface its antimicrobial activity [col 2, ln 57-64; col3, ln 24-30; col 5, ln 23-31]. Furthermore Sawan teaches that the antimicrobial activity of the polymer molecules is provided by an **additional substance**, for example a metallic material toxic to microorganisms such as silver, zinc, cadmium, lead, etc [col 9, ln 41-60]. The additional substance can be reversibly bound or complexed to the polymeric molecules. The additional substances are not polymeric and are not part of the polymeric chain of the polymeric molecules. Moreover, Sawan **never** says or suggests that the organic materials that coat the surfaces are inherently antimicrobial.

As previously mentioned, Sawan teaches that one adds an additional substance, such as silver ion, to the polymer to impart antimicrobial activity to the

organic material. Applicants further note that the Sawan inventors have published additional statements that imply that the organic materials they employ, particularly biguanides, are **not** inherently antimicrobial when bound to a substrate. See “A Chemically Intelligent Infection-Resistant Coating” by Suramanyam, Yurkovetskiy, Hale, and Sawan in “Antimicrobial/ Anti-Infective Materials, Ch. 9, p 221, S.P. Sawan and G Manivannan eds. Technomic Publishing Co., Inc. Published (2000). (Copy submitted herewith.) The authors of that article say that biguanides function as membrane-active bactericides only in solution (p. 223) and **have no bactericidal properties when immobilized on a surface** (p. 225). The authors provide experimental support at footnote 17a (p 236) and disclose that crosslinked polyhexamethylene biguanide coatings in the absence of silver iodide failed to reduce the *P. aeruginosa* population after over 20 hours at 30°C.

In summary, none of the types of organic materials taught by Sawan would suggest to one of ordinary skill in the art that polymeric molecules, **wherein said polymeric molecules are formed by the polymerization of a diallyldialkylammonium salt would have antimicrobial activity due to the presence of said polymeric molecules**, as recited in the claims under discussion.

We turn now to the secondary reference cited by the Examiner.

Perrault discloses a wound dressing formed from the polymerization of cationic quaternary amine acrylates or acrylamides monomers having pendant quaternary ammonium groups. The acrylate or acrylamide polymers are inherently antimicrobial and **when hydrated, provide hydrogel wound dressings**. The hydrogels can adhere to a wound to promote healing [col 3, ln 20-39]. The hydrogels can be prepared attached to a physical support structure, for example a patch [col 4, ln 48-57]. Perrault exemplifies in Formula II [col 4, ln 15-27] a typical structure of the acrylate and acrylamide polymers of his invention.

Perrault further discloses that the hydrogel wound dressing is inherently adhesive and preferably prepared with a physical support structure [col 4, ln 48-57]. The hydrogel is comprised of 15-95%, preferably 65-75%, quaternary ammonium polyacrylate. Therefore, the hydrogels of Perrault do not **consist essentially of** the quaternary ammonium polyacrylate. Furthermore, Perrault does not disclose or suggest polymeric molecules formed by the polymerization of a diallyldialkyl-ammonium salt as recited by Applicants in claim 30.

Assuming *arguendo* that if Sawan and Perrault were combined the result would meet the present claims (which it would not), Applicants assert that nevertheless, one of ordinary skill in the art would not have a reason to combine Sawan with Perrault because the references disclose different approaches toward antimicrobial polymers. Perrault teaches that forming a hydrogel is important to keep the wound moist during the healing process. Therefore, it is critical that the

monomers are capable of forming hydrogels. Perrault teaches that acrylamides and acrylate polymers are useful for forming hydrogels. Perrault does not teach or suggest that benzalkonium chloride derivatives, DMABHEAC, or biguanides disclosed by Sawan form hydrogels. Sawan teaches that an antimicrobial substance, such as silver ion, must be added to the polymer to impart antimicrobial activity to the polymer. Sawan does not teach or suggest that the polymers are components of hydrogels. It is impossible to envision how one of ordinary skill in the art would accommodate both Sawan's teaching of added antimicrobial substances (e.g. silver ion) and Perrault's teaching of water-absorbing hydrogels to make obvious Applicants invention.

Applicants further assert that incorporating the quaternary ammonium groups of Perrault within the organic materials of Sawan would not make obvious Applicants' invention for three reasons. *First*, Applicants teach that the polymeric molecules of claims 30 and 51 are derived from the class of monomers comprising diallyldialkylammonium salts. Neither reference discloses or suggests such monomers. *Second*, if one of ordinary skill in the art were able to combine the polymers of Sawan with those of Perrault, then the resulting polymer would not consist essentially of polymeric molecules formed by the polymerization of a diallyldialkylammonium salt. *Third*, Applicants teach that no additional substances are needed to produce antimicrobial activity.

Sawan teaches the addition of an antimicrobial substance such as silver ion to the polymer to provide antimicrobial activity. Sawan's teaching is contrary to Applicants' recitation in claim 30 of **a coating, layer, or enhanced surface area .... wherein said coating, layer, or enhanced surface area exhibits antimicrobial activity due to the presence of said polymeric molecules.** There is no reason for one of ordinary skill in the art, from reading Sawan, to conceive of using homopolymers or copolymers of diallyldialkylammonium salts bound to a substrate as producing an inherently antimicrobial composition.

Even if, hypothetically, one were to combine Sawan with Perrault (while ignoring Sawan's teaching of the use of an antimicrobial silver ion), nevertheless one would not produce Applicant's inherently antimicrobial compositions employing **polymeric molecules formed by the polymerization of a diallyldialkylammonium salt** or of DADMAC as recited in Applicants' claims 30 and 51.

Applicants further assert that because it would not have been obvious to one of ordinary skill in the art when the invention was made to have obtained Applicants' invention as recited in independent claims 30 and 51, it would also not have been obvious to obtain Applicants' invention as recited in claims 34-36, 44-46, 68, 69, 72, 86-89, 91, 93 and 94 which depend from the independent claims. Each of these claims recites, or depends from a claim that recites, that the polymeric

molecules are formed by the polymerization of a monomer in the class of diallyldialkylammonium salt monomers. Neither Sawan or Perrault, nor the combination of Sawan and Perrault, discloses or suggests the use of polymeric molecules formed by the polymerization of a diallyldialkylammonium salt.

Applicants respectfully request the Examiner to withdraw the obviousness rejection of the currently pending claims of this application and to allow the claims.

**B. REJECTION OF CLAIMS 67 AND 92 AS BEING UNPATENTABLE  
OVER SAWAN IN VIEW OF PERRAULT AND KOLB.**

The Examiner acknowledges that Sawan as modified by Perrault fails to disclose diallyldimethylammonium chloride (DADMAC). However, the Examiner asserts that Kolb teaches DADMAC and therefore it would be obvious to one of ordinary skill in the art to combine Kolb with Sawan and Perrault to obtain Applicants' invention as recited in claims 67 and 92. Applicants respectfully disagree.

Although Kolb refers to DADMAC [col 6, ln 26] in a wash list of "binding agents" that can be used to trap microorganisms, it fails to teach or suggest **polymeric molecules** formed by the polymerization of a diallyldimethylammonium salt or DADMAC as recited by Applicants in claims 67 and 92, respectively. Applicants assert that even if one of ordinary skill in the art were to ignore the inconsistent teachings and nevertheless seek to combine Kolb with Sawan and Perrault, the worker would not obtain Applicants' invention as recited in claims 67 and 92.

Applicants reassert their arguments given above regarding Sawan and Perrault as applied to claim 30. The addition of Kolb does not overcome the defects in the combination of Sawan and Perrault. Claims 67 and 92 depend from claim 30 and would also be patentable for the reasons cited above.

Furthermore, the combination of Perrault and Kolb, or Sawan and Kolb, do not make obvious Applicants invention as recited in claims 30 and 51. The teaching of DADMAC from Kolb combined with Sawan's teaching of a polymer having an additional substance to impart antimicrobial activity is inconsistent with Applicants' recitation in claims 30 and 51 of a polymer which exhibits antimicrobial activity due to the presence of said polymeric molecules. Therefore, the combination, of Perrault and Kolb, or Sawan and Kolb, do not make obvious Applicants' invention as recited in claims 30 and 51. Because claims 67 and 92, as well as, claims 31, 34-36, 44-46, 68, 69, 72, 86-89, 91, 93, and 994, depend from claim 30, none of these claims are made obvious by the various combinations of the references.

Applicants respectfully request the Examiner to withdraw the obviousness rejection of claims 67 and 92 and allow the claims and the remaining pending claims in the application.

#### 4. RESPONSE TO EXAMINER'S QUESTION AS TO SCOPE OF ENABLEMENT

There is no outstanding rejection of any claims as to Scope of Enablement. However, to expedite prosecution of this application, Applicants will also address the question raised by the Examiners during the telephone interview December 22, 2008.

35 U.S.C. § 112 (first paragraph) recites that the specification shall contain a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same..."

The Federal Circuit has interpreted the statute and said that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). MPEP § 2164.08.

Applicants assert that the recitation of polymeric molecules formed by the polymerization of a diallyldialkylammonium salt is enabled by the specification as filed. Given the disclosures within the specification, a person skilled in the art would be able to practice the invention. Applicants point to the specific disclosure of DADMAC in Table 1; the recitation of diallyldimethylammonium salts and similar compounds in claims 11-14, 25-28, and 39-42 as filed; the disclosure in paragraph [0096] of polymers based on DADMAC; and the general procedures for making polymeric quaternary ammonium compounds disclosed in paragraph [0035].

35 U.S.C. § 112 (first paragraph) is directed toward a person skilled in the art. Applicants assert that one skilled in the art would be an organic chemist who is familiar with customary synthetic procedures for preparing polymers, having at least a Bachelors degree in chemistry. The American Chemical Society publishes guidelines for curriculum and chemical information skills for a typical bachelors-

level chemist. Applicants refer the Examiner to “Undergraduate Profession Education in Chemistry”, ACS publisher, Spring, 2008 and “Chemical Information Retrieval”, ACS publisher, August 29, 2007. (Copies submitted herewith.) Such a skilled chemist would be able to review Applicants’ disclosure and to practice the full scope of the invention as currently claimed.

## CONCLUSIONS

Applicant intends this Response to be completely responsive to the outstanding Examiner’s Action. Since Applicant has amended claims 30, 31, 34-36, 45, 51, 67, 72, 91, and 92, canceled claims 33, 38, 39, 40, 42, and 90, added new claim 94, and provided arguments against the rejections, prompt notice of allowance of claims 30, 31, 34-36, 44-46, 51, 67-69, 72, 86-89, and 91-94 is respectfully solicited. If questions remain, the Examiner is invited to phone Applicant’s undersigned attorneys.

Respectfully submitted:

/s.m.p.m./

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